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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,107	11/03/2003	Steven P. Schwendeman	22727/04196	5145

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CALFEE HALTER & GRISWOLD, LLP
800 SUPERIOR AVENUE
SUITE 1400
CLEVELAND, OH 44114

EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/700,107	Applicant(s) SCHWENDEMAN ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges receipt of request for reconsideration, declaration under 37 CFR 1.132, terminal disclaimer and remarks, all filed 04/12/05. Claims 1-7 are pending.

Claim Rejections - 35 USC § 103

1. Claims 1-7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cleland et al. (US 5,643,605).

Applicants argue that:

- a) Cleland does not disclose or suggest biodegradable polymeric system whose microclimate is maintained during biodegradation at a pH of greater than 3.
 - b) Cleland does not disclose adding from about 10% to 30% (w/w) of a pore forming agent to PLGA to form a solution comprising pore forming agent and polymer and also that Cleland does not teach or suggest the use of poloxamer at a level of 10% to 30% (w/w) as a pore forming agent.
 - c) Cleland does not disclose or suggest the unexpected result of maintaining the microclimate at above pH 3 during biodegradation obtained by the addition of 10% to 30% pore forming agent (the declaration by Schwendeman is referenced).
2. Applicant's arguments filed 04/12/05 have been fully considered but they are not persuasive.

Cleland discloses biodegradable polymer. Cleland discloses PLGA microspheres for encapsulating adjuvants and Cleland incorporates preservatives, buffer or buffers, multiple excipients such as polyethylene glycol (PEG), mannitol and poloxamer non-ionic surfactants; 0.1% (w/v) to 30% (w/v) is the amount of non-ionic surfactant effective to provide stable,

Art Unit: 1618

aqueous formulations (column 9, lines 24-34). Thus Cleland suggests the use of PEG or poloxamer in amounts of 0.1% to 30% to maintain the stability of the formulation. If this is not sufficient and convincing suggestion by Cleland, it is noted that the person of ordinary skill in the art would know how to use the appropriate amounts of the PEG or poloxamer, pore forming agents, with respect to the PLGA to arrive at a desired pH. Moreover, Cleland's polymer is maintained at a pH of between 5-8 and at a preferred pH of 6.5-7.5, which is greater than pH 3. Since the PEG and the PLGA are in intimate association at a pH of 5-8, it would not just be the pH is only affecting the external environment of the polymer, but the polymer formulation is bathed in a solution at pH of 5-8 where the molecules of the PLGA and PEG or poloxamer are exposed to that pH. Cleland specifically refers to the PEG, mannitol, trehalose, non-ionic surfactants as excipients (column 9, lines 25-30). 1% to 30% pore-forming agent is added to the PLGA in Cleland and the pH is maintained at between 5 and 8 and this pH also is in the microclimate of the PLGA/PEG. Since the pH of the polymer is greater than 3, the relevance of an unexpected result of maintaining the pH of the microclimate of the polymer/PEG in the instant claims appears not to be unexpected. It is also noted that the claimed invention does not exclude the buffers disclosed by the prior art and the comprising language is open.

Declaration 1.132:

The instant claims do not recite antacids or other basic additives and whether the buffers of Cleland are weak bases or weak acids, the important disclosure is that the pH is maintained at pH 5-8. While the amount of PEG added to the PLGA is 100:1 to 1:100, allowing for maximum solubility of the polypeptide as declared by applicants, it is noted that ratio of 10:90 to 30:70 for PEG : Polymer referred to by Dr. Schwendeman is not claims and while the claims are read in

Art Unit: 1618

light of the specification, limitations from the specification are not read into the claims. The features upon which applicant relies in the declaration (i.e., 10 : 90 to about 30 : 70 for the PEG : Polymer) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The rejection is maintained above. *Applicants are further reminded that using Markush language to recite the pore forming agents from claims 3-6 in the generic claim and identifying the solvent used to dissolve the polymer may help with the prosecution of the application.* The specific solvents disclosed and contemplated may be recited using a Markush.

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1618

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594.

The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Blessing Fubara
Patent Examiner
Tech. Center 1600



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600